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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,476	01/31/2001	Glenn Friedrich	LEX-0126-USA	4146

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/773,476	FRIEDRICH ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1632.

Drawings

The corrected drawings filed 4/9/04 are not acceptable because Figure 2, having sheets 1-13, does not comply with 37 CFR 1.84(u), which requires that when partial views, e.g. sheets 1-13, are intended to form a single drawing, each of the separate views must be labeled by the same numeral followed by capital letters, e.g. Fig. 2A, Fig. 2B, Fig. 2C, ..., Fig. 2M. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 4-7 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons of record set forth in the Office action of 11/5/03.

Claims 1, 2, and 4-7 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed 4/9/04 have been fully considered but they are not persuasive. Applicant asserts (page 4) that the described mouse ES cells can be used to determine the physiological function of the mutated gene, and that when a mouse was made that carried a homozygous disruption in the gene that encodes the exon sequence set forth in SEQ ID NO: 294, the mouse developed cataracts at an early age. Applicant further asserts (page 5) that Fig. 2, page 6 of 7, line 23, "clearly discloses" the database annotation for SEQ ID NO: 294 as being similar to the human cDNA of W27087, and that this cDNA is the subject of two US patent applications,

and that the corresponding gene has been identified as encoding ARP-3. Applicant then argues that the claimed cells meet the requirements of §101 based upon these assertions.

In response, first of all, the claims are not limited to mouse ES cells. Second, there is no dispute that the ES cells generally described in the specification could potentially be used in the process of determining the physiological function of the mutated gene, assuming that a detectable phenotype results. Then, depending on the results of such a determination, one of skill in the art might be able to develop a specific and substantial use for the cells or products, e.g. a mouse, made with the cells. However, this use amounts to employing the cells as an object of research on the claimed invention to determine what effect, if any, the disruption has, and whether the resulting mouse has a "real-world" use. Such a use does not satisfy §101. *Brenner v. Manson*, 148 USPQ 689, 695-696 (US 1966).

With respect to the assertions directed specifically to SEQ IDNO: 294 corresponding to the ARP-3 gene and mice that are homozygous for a disruption in the corresponding gene, Applicant has provided no evidence to support these assertions. Furthermore, the specification does not direct one on how to interpret the information given in Figure 2, which does not identify SEQ ID NOs. Assuming that the lines in the list shown in original Fig. 2 correspond in order to SEQ ID NOs: 1-341, then line 23 would correspond to SEQ ID NO: 301, not SEQ ID NO: 294. The 294th line in original Fig. 2 refers to a mouse EST sequence W70839. (In later filed corrected drawings, Fig. 2 extends over more than 7 pages.) It must therefore be concluded that Fig. 2 does not clearly disclose the database annotation for SEQ ID NO: 294.

More importantly however, the utility requirement must be met at the time the application was filed, and the specification fails to teach that the gene corresponding to SEQ ID NO: 294 is

ARP-3, that mice homozygous for a disruption of the corresponding gene develop cataracts, or any use of the claimed cells based upon this information. The issue of whether the alleged new information would provide support for a specific and substantial utility is moot since that information was not present in the specification. The identification of a potential utility after an application has been filed does not serve to meet the utility requirement for that application. *In re Kirk*, 153 USPQ 48, 52-53 (CCPA 1967).

With respect to US 2002/0187523 and US 2003/0104559, these application were published on 12/12/02 and 6/5/03, respectively, which is long after the instant application was filed on 1/31/01. Consequently, their disclosures are not relevant to whether the instant application met the utility requirement as of its filing date. Applicant refers to a variety of US patents, in addition to these two applications. However, none of these references were supplied with the reply. Their disclosures were not considered.

Claims 1,2, and 4-7 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 11/5/03 as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 4/9/04 have been fully considered but they are not persuasive. Applicant argues that in order to have determined SEQ ID NO: 294, they must have possessed the ES cell line from which it was determined. In response, the claims are not limited to the particular mouse ES cell line form which SEQ ID NO: 294 was determined. The rejection

was not based upon whether Applicant possessed this species of mouse ES cell, but whether the specification provided an adequate written description of the genus of cells being claimed. First, claims 1 and 4-6 embrace any mammalian cell, and claim 2 embraces any murine cell, not just mouse cells or mouse ES cells. Second, the claims embrace cells with a disruption in any gene "identifiable as corresponding to SEQ ID NO: 294", not just the specific mouse ES cell described in the specification. Third, the claims embrace cells in any part of a gene "identifiable as corresponding to SEQ ID NO: 294," not just a gene trap insert upstream of SEQ ID NO: 294 in a mouse cell. In order to make the mammalian cell as broadly as it is claimed, one must know the identity of genes "identifiable as corresponding to SEQ ID NO: 294" and be is possession of the genus of DNA molecules required to direct insertion of the "recombinantly manipulated polynucleotide sequence." The instant specification only provides SEQ ID NO: 294. It does not describe any other sequence from the mouse gene comprising SEQ ID NO: 294, or any nucleotide sequence information whatsoever from any other genes "identifiable as corresponding to SEQ ID NO: 294" in a mouse, in any other murine, e.g. Norway rat, or any other mammal, e.g. domestic dog.

With respect to Applicant's arguments concerning ARP-3, the specification does not mention this gene at all, and Applicant has provided no evidence that they possessed this knowledge at the time the invention was made.

Claims 1, 2 and 4-6 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 4/9/04 have been fully considered but they are not fully persuasive. Applicant's arguments are convincing with respect to the first and third grounds of rejection, but not the second, concerning the meaning of "gene identifiable as corresponding to SEQ ID NO: 294." Applicant argues that one of skill in the art would understand that the gene would be the ARP-3 locus. However, as indicated above, the specification makes no mention of ARP-3, and at the time the instant invention was made, one of skill in the art would have no such understanding. The metes and bounds of this limitation are unclear because the neither the specification nor the claims indicates the nature or extent of the correspondence between SEQ ID NO: 294 and any gene other than perhaps the specific gene that was disrupted in the disclosed mouse ES cell from which SEQ ID NO: 294 was determined. It is unclear, for example, whether the "corresponding" gene is limited to the gene disrupted in the mouse ES cells, or also includes orthologs in other mammalian cells, or also includes paralogs in mouse and other mammalian cells, or also includes genes that have homology in only specific parts or regions, e.g. homology in a region that encodes a specific peptide motif.

This rejection would be overcome by limiting the cell to a mouse cell and the "corresponding" gene to a mouse gene that encodes SEQ ID NO: 294, as in claim 7.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe
Primary Examiner
Art Unit 1632